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09/890,729	08/03/2001	Steven Kiyoshi Yoshinaga	A-579B	7722

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M. PAUL BARKER, ESQ
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WASHINGTON, DC 20005-3315

EXAMINER

OUSPENSKI, ILIA I

ART UNIT PAPER NUMBER

1644

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,729	Applicant(s) YOSHINAGA, STEVEN KIYOSHI	
	Examiner ILIA OUSPENSKI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 19-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18, 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 08/26/2004, is acknowledged.

2. Applicant's election with traverse of the Invention of Group 4, drawn to antibodies to B7RP1, in the reply filed on 08/26/2004 is acknowledged. The traversal is on the ground(s) that US20020164697 does not anticipate Claim 1 of the instant application. This is not found persuasive because US20020164697 discloses a nucleic acid sequence which anticipates Claim 1.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1 – 12 and 19 - 31 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions.

Claims 13 and 14 have been amended.

Claim 32 has been added.

Claims 1 – 32 are pending.

Claims 13 – 18 and 32 are under consideration in the instant application.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth herein.

Upon review of the instant application, it is noted that the sequences disclosed at least on page 93, first paragraph, *are not accompanied by SEQ ID Numbers*. Applicant

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is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules. Applicant is reminded to amend the specification and the claims accordingly.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) in response to this Office Action.

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

The application claims benefit to international application No. PCT/US00/01871 filed on 01/27/2000. Applications that are filed on or after November 29, 2000, and that claim benefit to an earlier-filed international application must include in the first sentence of the specification an indication of whether the international application was published in English under PCT Article 21(2) (regardless of whether the benefit for such application is claimed in an application data sheet). See 37 CFR 1.78(a)(2). The indication, as required by 37 CFR 1.78(a)(2), is missing. Applicant must supply the missing indication as an amendment to the specification in the reply to this Office action.

5. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The application USSN 09/264,527 upon which priority is claimed appears to provide adequate support under 35 U.S.C. 112 for subject matter claimed in the instant application.

However, the application USSN 09/244,448 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for SEQ ID NOS: 16 and 17 of this

application. The instant claims as they read on SEQ ID NOS:16 and 17 have thus been accorded the priority of the filing date of USSN 09/264,527, i.e. 03/08/1999.

Should Applicant disagree with the Examiner's factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

7. Applicant's communications entitled "Information disclosure Statement," filed 12/06/2001 and 02/06/2003, are acknowledged. The communications state that document listings on Form PTO-1449 are attached, however, such forms could not be found in the instant file. Applicant is invited to resubmit such forms and references to complete the file. The examiner apologizes for any inconvenience to applicant for having to resubmit such documents.

8. The use of the trademarks (e.g. Trizol on page 71) has been noted in this application. Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

In addition, Applicant is requested to review the application for embedded hyperlinks and/or other forms of browser-executable code and delete them. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. See MPEP § 608.01 and 608.01(p).

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9. Claim 13 is objected to because of the following informalities: the SEQ ID NOS recited in 13(c) correspond to nucleic acid sequences, whereas amino acid sequences were apparently intended.

For examination purposes, it is assumed that claim 13(c) reads "the polypeptide as set forth in Figure 2A (SEQ ID NO:7), Figure 3A (SEQ ID NO:12, or Figure 12A (SEQ ID NO:17)."

Appropriate correction or clarification is required.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 13 – 18 and 32 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claims 13 – 18 are indefinite in the recitation of "hybridization under stringent conditions." Although the specification discloses on pages 23 – 24 examples of such conditions, in the absence of a clear definition of the metes and bounds of this phrase it is unclear which conditions are actually claimed.

It is suggested that Applicant amend the claims to recite a particular set of hybridization and wash conditions to overcome this rejection.

(B) Claim 32 is indefinite in the recitation of an "ortholog," because the metes and bound of the claimed invention are unclear. Although the general meaning of word

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“ortholog” as a gene or a protein related to the disclosed gene or protein via common ancestry (see e.g. Life Science Dictionary definition, entry attached) is known in the art, the degree of relatedness is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree. Thus the use of the term “ortholog” renders the claim vague and indefinite.

(C) Claims 13 – 18 and 32 are indefinite in the recitation of “an allelic variant or alternative splice variant of (a), (b), (c),” because the metes and bound of the claimed invention are unclear. Although the terms “allelic variant” and “splice variant” are defined in the specification on page 23, it is clear from the provided definitions that that the terms are applicable to a “gene” or “transcript,” i.e. full-length molecules. Thus the meaning of the terms as applied to fragments or genes or transcripts, as in claim 32 (a), (b), and (c), is unclear. It is noted that SEQ ID NOS:6 and 7 apparently represent only a part or a fragment of human B7RP1 cDNA and protein, respectively. Thus one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

(D) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 13 – 18 and 32 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, *while being enabling for*.

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antibodies or fragments thereof which bind to polypeptides encoded by nucleic acid molecules consisting of SEQ ID NOS:6, 11, or 16, or specifically disclosed fragments thereof, and to polypeptides consisting of SEQ ID NOS:7, 12, or 17, or specifically disclosed fragments thereof,

does not reasonably provide enablement for antibodies or fragments thereof which bind to a polypeptide

(1) encoded by a nucleic acid comprising

the nucleotide sequences as set forth in SEQ ID NOS:6, 11, or 16, or fragments thereof;

a nucleotide sequences encoding a polypeptide that is at least about 70 percent identical to SEQ ID NOS:7, 12, or 17;

a naturally occurring allelic variant or alternate splice variant;

a nucleotide sequence which hybridizes under stringent conditions to the complementary sequence of any of the above; or

(2) comprising the amino acid sequence

as set forth in SEQ ID NOS:7, 12, or 17;

a fragment thereof;

an ortholog thereof; or

an allelic variant or alternative splice variant.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims.

(A) "Comprising" language.

The term “comprising” in claims 13 and 32 is open-ended and extends the polypeptide to include additional non-disclosed sequences on either or both sides of the disclosed region. As there are no limitations on the sequence or size of these undisclosed sequences, there does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would make and use the plethora of antibodies which would bind to such sequences. A person of skill in the art would not know which sequences to select for making and using the claimed antibodies commensurate with the scope of the claims, other than the polypeptide limited to disclosed sequences and specifically identified fragments of the instant claims.

(B) Allelic variants and splice variants.

The term “allelic variants” encompasses “one of several possible naturally occurring alternate forms of a gene occupying a given locus on a chromosome of an organism,” as disclosed in the specification as-filed on page 23. Similarly, a “splice variant” is a reference to “a nucleic acid molecule, usually RNA, which is generated by alternative processing of intron sequences in an RNA transcript” (page 23). Applicant has not provided sufficient biochemical information (e.g. nucleic acid sequences, etc.) that distinctly identifies the *allelic variants or splice variants* of the claimed molecules, other than those set forth in SEQ ID NOS:6, 11, and 16.

It is not sufficient to define a specificity by its principal biological activity or structure, e.g. for allelic variants or splice variants of SEQ ID NOS:6, 11, or 16, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. The specification appears to provide insufficient data on the existence of allelic variants or splice variants of the claimed molecules.

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Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use of the claimed protein in manner reasonably correlated with the scope of the claims broadly including antibodies to any number of allelic variants or splice variants of SEQ ID NOS:6, 11, or 16. The scope of the claims must bear a reasonable correlation with the scope of enablement. The specification does not provide for sufficient enablement for allelic variants or splice variants of the claimed molecules other than those defined by SEQ ID NOS:6, 11, or 16.

(C) Hybridization and percent identity language.

The claims encompass a genus of antibodies that bind to polypeptides which have numerous differences in amino acid sequences, as allowed by the hybridization and percent identity language.

However, the present specification fails to provide sufficient disclosure of such polypeptides that maintain the structural and functional properties of the B7RP1 polypeptides set forth in SEQ ID NOS7, 12, and 17. The specification does not provide sufficient guidance as to which of the amino acids may be changed while B7RP1 structural or functional activity and specificity is retained.

Colman et al. (Research in Immunology, 1994; 145(1): 33-36) teach that single amino acid changes in an antigen can effectively abolish antibody antigen binding. Abaza et al. (Journal of Protein Chemistry, Vol. 11, No. 5, 1992, pages 433-444) teaches single amino acid substitutions outside the antigenic site on a protein effect antibody binding. Further, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Additionally, Li et al. (PNAS 77: 3211-3214, 1980) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

Because of this lack of guidance, the extended experimentation that would be required to determine which modifications would be acceptable to retain occluding structural and functional activity, and the fact that the relationship between the sequence of a protein/peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g. see Ngo et al.; in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), it would require an undue amount of experimentation for one of skill in the art to arrive at the antibodies which bind polypeptides different in sequence from those set forth as SEQ ID NOS:7, 11, and 17.

The scope of the claimed antibodies is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claimed invention as recited in claims 13 and 32. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's or peptide's amino acid sequence, and, in turn, nucleic acid sequence, and still retain similar biological activity or structural specificity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a limited number of proteins/nucleic acids and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex and well outside the realm of routine experimentation.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use of the claimed antibodies in manner reasonably correlated with the scope of the claims broadly including a broad number of structural changes encompassed by the genus of polypeptides as recited in claims 13 and 32.

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The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 19 24 (CCPA 1970). Without such guidance, the changes which can be made in the claimed nucleic acids and amino acids and still maintain biological activity or structural specificity of B7RP1 proteins is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

14. Claim 13 – 18 and 32 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

Applicant is in possession of antibodies or fragments thereof which bind to polypeptides encoded by nucleic acid molecules consisting of SEQ ID NOS:6, 11, or 16, or specifically disclosed fragments thereof, and to polypeptides consisting of SEQ ID NOS:7, 12, or 17, or specifically disclosed fragments thereof.

Applicant is NOT in possession of antibodies or fragments thereof which bind to a polypeptide

(1) encoded by a nucleic acid comprising

the nucleotide sequences as set forth in SEQ ID NOS:6, 11, or 16, or fragments thereof;

a nucleotide sequences encoding a polypeptide that is at least about 70 percent identical to SEQ ID NOS:7, 12, or 17;

a naturally occurring allelic variant or alternate splice variant;

a nucleotide sequence which hybridizes under stringent conditions to the complementary sequence of any of the above; or

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(2) comprising the amino acid sequence

as set forth in SEQ ID NOS:7, 12, or 17;

a fragment thereof;

an ortholog thereof; or

an allelic variant or alternative splice variant.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for the following reasons:

(A) "Comprising" language.

The term "comprising" in claims 13 and 32 is open-ended and extends the polypeptide to include additional non-disclosed sequences on either or both sides of the disclosed region. As there are no limitations on the sequence or size of these undisclosed sequences, the claimed invention is not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A person of skill in the

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art would not know which sequences are encompassed by the written description of the claimed antibodies commensurate with the scope of the claims, other than the polypeptide limited to disclosed sequences and specifically identified fragments of the instant claims.

(B) Allelic variants and splice variants.

The term “allelic variants” encompasses “one of several possible naturally occurring alternate forms of a gene occupying a given locus on a chromosome of an organism,” as disclosed in the specification as-filed on page 23. Similarly, a “splice variant” is a reference to “a nucleic acid molecule, usually RNA, which is generated by alternative processing of intron sequences in an RNA transcript” (page 23). Applicant has not provided sufficient written description (e.g. nucleic acid sequences, etc.) that distinctly identifies the *allelic variants* or *splice variants* of the claimed molecules, other than those set forth in SEQ ID NOS:6, 11, and 16.

It is not sufficient to define a specificity by its principal biological activity or structure, e.g. for allelic variants or splice variants of SEQ ID NOS:6, 11, or 16, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. The specification appears to provide insufficient written description on the existence of allelic variants or splice variants of the claimed molecules.

Thus, applicant has not provided sufficient written description of the invention to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the allelic variants or splice variants of the claimed molecules other than those defined by SEQ ID NOS:6, 11, or 16.

(C) Hybridization and percent identity language.

The claims encompass a genus of antibodies that bind to polypeptides which have numerous differences in amino acid sequences, as allowed by the hybridization and percent identity language.

However, the present specification fails to provide sufficient written description of such polypeptides that maintain the structural and functional properties of the B7RP1 polypeptides set forth in SEQ ID NOS 7, 12, and 17. The specification does not provide sufficient written description as to which of the amino acids may be changed while B7RP1 structural or functional activity and specificity is retained.

Colman et al. (Research in Immunology, 1994; 145(1): 33-36) teach that single amino acid changes in an antigen can effectively abolish antibody antigen binding. Abaza et al. (Journal of Protein Chemistry, Vol. 11, No. 5, 1992, pages 433-444) teaches single amino acid substitutions outside the antigenic site on a protein effect antibody binding. Further, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Additionally, Li et al. (PNAS 77: 3211-3214, 1980) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

Because of this lack of written description as to which modifications would be acceptable to retain occluding structural and functional activity, and the fact that the relationship between the sequence of a protein/peptide and its tertiary structure (i.e. its activity) are not well understood (e.g. see Ngo et al.; in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.), the specification fails to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of antibodies which bind to polypeptides different in sequence from those set forth as SEQ ID NOS: 7, 11, and 17.

The scope of the claimed antibodies is not commensurate with the scope of written description provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claimed invention as recited in claims 13 and 32. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's or peptide's amino acid sequence, and, in turn, nucleic acid sequence, and still retain similar biological activity or structural specificity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, the problem of deducing protein structure from mere sequence data of a limited number of proteins/nucleic acids and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex and well outside the scope of written description provided.

Thus, applicant has not provided sufficient written description of the invention to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed antibodies in manner reasonably correlated with the scope of the claims broadly including a large number of structural changes encompassed by the genus of polypeptides as recited in claims 13 and 32.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

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The specification therefore fails to provide an adequate written description of the above noted claim limitations. As noted supra, the skilled artisan would not reasonably expect a polypeptide different in sequence from those set forth as SEQ ID NOS:7, 12, and 17 to share the same function as B7RP1. Even though the specification describes general procedures for generating antibodies, it does not set forth any procedure that will necessarily lead to production of the claimed antibodies, nor does it even identify any particular example of such antibodies to variant sequences.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

15. Conclusion: no claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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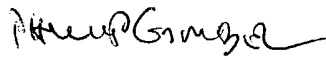
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ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

November 8, 2004


PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TOL4 CENTER 1600
11/9/2004